K112033

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510(k) Summary

Company Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact Donovan May
Regulatory Affairs Associate II
Ethicon Endo-Surgery, Inc.
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Date Prepared July 14, 2011

Device Name Trade Name: ENSEAL® G2 Tissue Sealers
Common Name: Electrosurgical Cutting and Coagulating Instrument

Classification Names

- Electrosurgical, Cutting & Coagulation & Accessories (21 CFR 878.4400, Product Code GEI)
- Electrocautery, Gynecologic and Accessories (21 CFR 884.4120, Product Code HGI)

Predicate Devices

ENSEAL Tissue Sealing Devices cleared under K072177 on August 29, 2007 and K072493 on September 5, 2007 as part of the ENSEAL Vessel Sealing and Hemostasis System

Device Description:

The Ethicon Endo-Surgery ENSEAL G2 Tissue Sealers are for bipolar coagulation and mechanical transection of tissue during laparoscopic and open procedures. The devices allow the surgeon to grasp, coagulate, and transect soft tissue with a single instrument. The devices are hand-actuated with a shaft and tissue effector that can be rotated. The energy delivery can be activated with hand activation or with a foot switch.

Indications for Use:

The ENSEAL G2 Tissue Sealers are indicated for bipolar coagulation and mechanical transection of tissue during laparoscopic and open procedures.

The devices are bipolar electrosurgical instruments for use with an electrosurgical generator. They are intended for use during open or laparoscopic, general and gynecological surgery to cut and seal vessels, and to cut, grasp and dissect tissue during surgery.

Indications for use include open and laparoscopic, general and gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection is performed. The devices can be used on vessels up to (and including) 7 mm and bundles as large as will fit in the jaws of the instruments.

The ENSEAL G2 Tissue Sealers have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use these devices for these procedures.

The predicate devices were submitted as part of a surgical system; thus, the Indications for Use statements cleared in the predicate submissions did not contain indication language specific to the function of the electrosurgical instruments except for those included in the labeling. Additionally, the electrosurgical energy type (bipolar) and means of transection (mechanical) were added to the Indications for Use statement for the subject devices. This additional information was added for clarity. These differences in the indications for use do not alter the intended surgical effects or intended use of the subject devices from that of the predicate devices.

Technological Characteristics: The Ethicon Endo-Surgery ENSEAL G2 Tissue Sealers incorporate the same technological characteristics as that of the predicate devices with an ergonomic handle and an integrated energy activation/knife release button. Additionally, a change was made to a patient contacting material of the 3 mm jaw version of the subject devices.

Performance Data: Bench testing and laboratory evaluations in an animal model including an acute and a 30-day chronic survival study were conducted to demonstrate that the Ethicon Endo-Surgery ENSEAL G2 Tissue Sealers perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV - 8 2011

Ethicon Endo-Surgery, Inc.
% Mr. Donovan May
4545 Creek Road
Cincinnati, Ohio 45242

Re: K112033
Trade/Device Name: ENSEAL® G2 Tissue Sealers
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, HGI
Dated: October 07, 2011
Received: October 11, 2011

Dear Mr. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K112033

Device Name: ENSEAL® G2 Tissue Sealers

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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